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(54) **Pin plate**

Platte und Stift

Plaque et pointe

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EP-A- 0 382 256
FR-A- 2 501 033
GB-A- 2 158 716
FR-A- 2 291 734
GB-A- 1 300 449

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Description

[0001] The present invention relates to an implantable means according to the preamble of the independent claim.

[0002] A fracture near a joint has always been difficult to treat, as the ideal treatment is to achieve rigid fixation of the fracture fragments while allowing nearly immediate motion of the joint.

[0003] In order to simplify the description the present invention is described in connection with fractures about the wrist, and particularly those fractures collectively referred to as Colles' fractures. A person skilled in the art will appreciate that the invention is also applicable in fixation of other bones. Possible other bones include, but are not limited to, the distal or lower end of the humerus, the lower tibia and the lower fibula. This requires a change of the shape of the device for each specific area, but the same principles are used irrespective of the site of the fracture. However, the major use of the invention is thought to be for fixation of Colles' fractures.

[0004] Treatment of distal radius fractures has been a problem, both because of the frequency of the injury as well as the difficulty in treating them. The goal of treatment is to restore joint congruity and anatomy, minimize the risk of arthritis, and maximize joint mobility. However, although these injuries are almost always treated on an outpatient basis, they typically result in stiffness, arthritis, and diminished function.

[0005] GB 2 158 716 discloses a bone joining plate having a predetermined shape whereby the plate is conformable with the surface of a preselected bone. The plate includes a plurality of holes for receiving fastening elements and one or more pointed members integral with the plate for bending and insertion into the preselected bone. The plate is intended to secure a near-joint or joint fracture without the use of an external pin.

[0006] GB-A-1 300 449 discloses an implantable device as defined in the preamble of claim 1.

[0007] There are today essentially four general groups of options available for the treatment of Colles' fractures: (1) closed reduction and casting, (2) external fixation, (3) open reduction and internal fixation, and (4) percutaneous pinning and/or limited open pinning. Each method has its limitations; each has its benefits.

[0008] Closed reduction simply involves setting or aligning the broken bone manually and applying a cast to the arm. This treatment avoids any trauma associated with surgery, and is cheaper to the medical system. However, it has several disadvantages. It involves cast immobilization until healing of the bone fragments occurs; this frequently results in considerable stiffness. This stiffness is not just confined to the wrist and forearm. Immobilizing the arm in an elderly individual frequently also results in considerable stiffness to the fingers, elbow, and shoulder as well. In addition, this technique is very limited in its ability to hold all but the simplest, most stable fracture patterns in proper alignment. Unstable fractures commonly redisplace during healing, which can lead to arthritis and pain.

[0009] External fixation involves the application of relatively large diameter pins inserted into the finger metacarpals and into the radius above the fracture. These pin clusters are then connected with a bar or frame, essentially "bypassing" the fracture site. Typically, two pins are placed in the hand, and two pins in the radius. The frame may distract the wrist as well, in order to assist with fracture reduction, by using the soft tissue sleeve around the fracture to help squeeze the fragments into position. Although external fixation has its proponents, it has its problems. The wrist and hand are rigidly held by the frame, and the pins through the skin tend to irritate the tendons and cause scarring. These problems together cause considerable stiffness in both the wrist and the fingers; frequently the functional loss of grip can be more disabling than the fracture. Pin site infections may also occur and compromise results. External fixation may not achieve an anatomic reduction of the fragments. Currently, external fixation is used for more severely comminuted, fragmented fractures.

[0010] Open reduction involves making an incision over the wrist reducing the fragments, and applying plates, screws, and pins as needed. For the Colles' fracture open reduction and internal fixation is seldom used, for several reasons. First, the trauma associated with the dissection and exposure can lead to scarring of the tendons, loss of gliding, and stiffness. Second, the dissection can compromise the blood supply to the fragments, which can result in delayed unions and occasionally non-unions. Third, the fragments tend to be small and osteoporotic; drilling holes and placing screws frequently fragments these pieces further, making anatomic reduction even more difficult. Fourth, most of the fragments and displacement in the typical Colles' fracture are on the dorsal side, and the irregularity of the radius in this area together with the many tendons found near the bone on this side makes it undesirable to place plates and screws dorsally. Finally, these fractures are often comprised of numerous small pieces which must be reduced in a jigsaw puzzle type of arrangement, not easily treated by plate and screw fixation.

[0011] Percutaneous pinning involves the placement of small stiff pins, also called K-wires, across fragments of the fracture. The pins may be inserted directly through the skin while imaging the fracture with a fluoroscopy unit. Limited small incisions may also be used. Typically, pin diameters range from 0.889 to 1.575 mm (from 0.035" to 0.062"), with the 1.143 mm (0.045") and 1.372 mm (0.054") pin sizes commonly used in the USA. Pinning has certain advantages. Using a percutaneous or limited open technique to pin fragments allows the fracture to be internally fixed. This provides some additional stability internally which is not available when the fracture is treated with a cast alone. The fragments in these fractures tend to be small and the bone osteoporotic. As a result, pins are more appropriate as a type of fixation

than screws in this setting. A small diameter pin has less chance of weakening the fragment and comminuting it further compared with screw holes that are made with even small diameter bone screws.

[0012] Pinning, however, has its problems. In order to secure a fragment, there must be a stable bone nearby for securing the pin. Frequently, the only stable piece of bone is the proximal fragment, which may be some distance and at a difficult angle away from the fragment to be pinned. Since the pins have a small diameter, they are likely to bend or displace if the stable piece of bone is relatively far from the fracture fragment. This reduces the ability of the pin to maintain the position of the fragment and, in turn, impedes the process of healing.

[0013] In certain cases multiple fragments are put together like stacking cards, by fixing one fragment to a stable proximal piece, and then pinning a second fragment to the first piece, which is assumed to be stabilized by the first pin. This frequently makes the entire assembly dependent upon one or two pins which may engage the stable proximal cortex at some distance from the fracture fragment. Such situations are often unstable.

[0014] Another problem with pinning is that the stable piece of bone that the fragment is pinned to has to be located on the opposite cortex from where the pin is inserted. If the only nearby solid piece of bone is located on the cortex adjacent to the fracture fragment, pinning becomes a geometric impossibility. This situation occurs frequently when a dorsal ulnar fragment occurs. If the opposite volar radial surface is fractured in such cases as is often the case, there is no stable cortex available to the angles of pin insertion that are technically feasible.

[0015] Examples of these problems with pinning are often encountered in treatment of Colles' fractures involving a radial styloid fragment fixed by a percutaneous trans-styloid pin. The fracture is reduced, and the fluoroscopy unit is used to pass a pin through the radial styloid on an angle to engage the ulnar cortex proximal to the distal fragment. The ability of the pin to hold the radial styloid fracture fragment in an appropriate position is dependent upon the fixation of the pin in the stable proximal ulnar cortex. Since the distance to this fixation site is quite far, and because the small diameter of the pin permits bending, small angular deflections of the pin in its site of purchase at the proximal fragment may lead to significant displacements of the fractured radial styloid.

[0016] Because pins have a strong tendency to bend and displace due to motion of the joint, pins are hardly ever used without casting. This means that the patient is still subjected to the common complications of stiffness and loss of function that is associated with the cast.

[0017] Ideally the treatment of distal radius fractures should have the same goal as treatment of any other fracture near a joint, namely, achieving rigid fixation of the fracture fragments while allowing nearly immediate mobility of the joint. As can be seen from this discussion, none of the current methods of treatment achieves this goal. Pins alone do not provide adequate stability by themselves and still require a cast. External fixation allows rigid fixation, but does not allow direct reduction of the fracture site, and is associated with considerable morbidity from the complications of stiffness. Closed reduction may cause stiffness as well, and frequently fails to preserve anatomic reduction.

[0018] One primary objective of the present invention is to satisfy the goal of providing rigid fixation of fracture fragments while allowing immediate motion of a joint. This objective is satisfied using the technique disclosed in the characterizing clause of the independent claim which follows. The means according to the invention provides an implantable way of constraining by direct contact one or more pins which have been placed to secure fractured bone fragments.

[0019] Expedient embodiments of the present invention are disclosed in the dependent claims.

[0020] The present invention will now be described in greater detail hereinbelow, with the aid of embodiments shown in the drawings. In the accompanying drawings:

Fig. 1	is a top view of a radial pin plate according to one embodiment of the invention;
Fig. 2	is a side view of the pin plate of Fig. 1;
Fig. 3	is an end view of the pin plate of the previous Figs.;
Fig. 4	is an exploded view of one embodiment of the invention;
Fig. 5	shows one embodiment of the invention fixed to the radius;
Fig. 6	shows one embodiment of the invention fixed in an alternative location to the radius;
Fig. 7a-7c	are top, side and end views, respectively, of an ulnar pin plate according to the invention.

[0021] As used herein the expression "pin" also covers wire, nail with head or headless, pins with bent parts, pins having a head. The difference between "pins" and "wires" in this case is only the diameters, small diameter ones are called wires and larger diameter ones are called pins. Thus, to simplify the description the term "pin" is intended to cover all of the above and similar devices in the description hereinbelow.

[0022] Furthermore, the expression "fastening screws" is used for simplicity in the description of securing the plate to bone, but the fastening means are not limited to screws. In other embodiments pins, wires, blades, staples, brackets, or indirect coaption with an-

other device securely attached to the stable bone fragment through holes in the plate are used.

[0023] In the embodiment of the invention shown in Figs. 1 to 5 the implant consists of a pin plate 1 having apertures 2, 3 for fastening screws 7 or pins 8, respectively. One or more of the holes 3 for receiving pins 8 is in some embodiments furnished with slots 4 for insertion of the pins 8 in a way to be described below. In some embodiments the holes 3 are chamfered to facilitate the insertion of the pins 8.

[0024] The pin plate 1 is designed to have a form adapted to the intended place of use. The general form of the radial pin plate 1 is apparent from Figs. 1 to 3. As is apparent from Figs. 4 and 5 the upper part of the radial pin plate 1 follows the form of the radial styloid and has a straight cross-section in end view. The lower part of the pin plate 1 has a semicircular cross-section in end view (Fig. 3) to match the form of the radius on the dorsal side.

[0025] Separate left and right pin plates 1 are furnished as well as pin plates with varying lengths. In the embodiment of the drawings the pins 8 have a circular cross-section. In other embodiments of the invention the pins 8 have other cross-sections, such as triangular, quadrangular, trapezoid etc. Furthermore, in some embodiments the lower part of the pins 8 have one cross-section, e.g. round, and the upper part another cross-section, e.g. quadrangular. In order to match pins 8 with different diameters various plate hole sizes are available. In one embodiment the pin plate 1 is furnished with holes 3 accepting pins 8 with different diameters. The actual dimensions to be used is decided by the surgeon in each case based on the specific circumstances such as fracture site, fragment size, bone condition etc.

[0026] Figs. 7a to 7c show one embodiment for an ulnar pin plate 1', i.e. a pin plate 1' adapted for use on the ulna. The most apparent difference between the radial pin plate 1 and the ulnar pin plate 1' is the form of the cross-section in end view. The lower part of the ulnar pin plate 1' has a straight cross-section (Fig. 7c). Apart from the somewhat different form the ulnar pin plate 1' displays the same features as the radial pin plate 1. Thus, the ulnar pin plate 1' has apertures 2', 3' and a slot 4' for cooperation with fastening screws and pins, respectively.

[0027] The rigidity of pin fixation of the fracture fragment is considerably improved by having it pass through one of the small holes 3 and possibly a tight slot 4 in the pin plate 1 which has been secured to the proximal fragment 10. After the pin 8 is placed, it can be bent over the superficial surface of the plate 1 to keep it from migrating. The pin 8 now has two point fixation, and fragment stability is greatly enhanced. In addition, the plate can serve an additional role as a buttress to the distal fragment 9.

[0028] The pin plate 1 is securely fixed proximally with one or more screw(s) 7, pin(s), wire(s), blade(s), staple (s) bracket(s) or indirect coaptation with another device to the stable bone fragment through holes in the plate. The plate has distally holes 3 through which the pin 8 is passed; additionally, these holes 3 may or may not have slots 4.

[0029] If a hole 3 with a slot 4 at the distal portion 5 of the plate 1 is used, the pin 8 will be placed first, and the plate 1 slid along the surface of the bone 10 to engage the pin 8. In one embodiment the entrance slot 4 is slightly undersized, and capable of slight widening as the pin passes through the slot. This way, the plate 1 will "snap" as the pin 8 is passed into the slot 4, preventing disengagement. Once the plate 1 is snapped over the pin 8, the pin 8 is bent to further secure it, and the plate 1 is fixed proximally with one or two screws 7 or other means of fixation, as indicated above.

[0030] Normally the pin, or K-wire, is placed on a high speed drill type apparatus, known as a pin driver, or it may be placed on a standard sterile operating room drill. In different embodiments the tip of the pin is either a trochar type, or narrows to a flattened region near the end which ends in a point. Some designs have a cutting type drill bit on the end. Thus, the tip of the pin acts like a drill and allows the tip to cut through bone as it is inserted.

[0031] The fixation of the pins 8 at the pin plate 1 is accomplished in different ways in different embodiments of the invention. In one embodiment the pins 8 are bent over the superficial surface of the plate 1 as stated above.

[0032] In a further embodiment (not shown) the openings 3 for receiving the pins 8 are slightly undersized with a cut extending from the hole 3 to the edge of the plate 1. In this design the pin 8 is captured at the site of insertion due to the compression of the surrounding undersized hole. In this situation, a three-pointed clamp is applied to the plate to place a bending torque on the plate centered at the site of the pin hole 3; this allows the hole 3 to be enlarged or opened up slightly, enough so that it allows placement of the pin 8 through the hole 3. When the clamp is released, the hole 3 returns to its normal outer diameter, holding the pin 8.

[0033] Alternatively, a slotted hole 3 is used which joins a slightly undersized hole 3, instead of a slightly larger hole. In this circumstance, as the pin 8 is snapped into the hole 3, it is effectively locked into place.

[0034] The focus of this device is in securing a trans-styloid radial pin 8. It makes the fixation of this fragment secure enough so that a cast is not necessary in most cases. Each plate 1 allows one or more pins 8 in the distal end. The number of pins 8 used and their angle of insertion is decided in each case by the surgeon depending on the site and size of the specific fracture or fractures. In some instances the pin 8 is inserted through the fragment to engage a stable piece of bone on the other side of the fragment. In other instances the pin is only inserted in the adjacent cortex.

[0035] In Fig. 5 a pin plate 1 according to the invention is shown in an embodiment for fixation of a trans-styloid pin 8.

[0036] In Fig. 6 an alternative pin plate 1 is shown with a design to match the contour of the bone at the ulnar, dorsal side of the distal radius. This pin plate 1 is intended for use when there is a need to place a pin from that side of the distal radius.

[0037] The implant of the invention has further applicability in fixation of other bones besides the radius.

[0038] The above detailed description has referred to but a limited number of embodiments of the present invention, but it will be readily perceived by a person skilled in the art that the present invention encompasses a large number of embodiments without departing from the scope of the appended claims.

Claims

1. An implantable device for fixation of at least one fractured bone fragment (9) to a stable bone fragment (10), said implantable device comprising an implantable plate (1) having opposite end portions, fastening means (7) for securing one end portion of said plate to the stable bone fragment, at least one fixation pin (8) to be placed across a fracture for provisional stabilization of the unstable bone fragment (9) to the stable bone fragment (10), wherein the other end portion of the plate (1) contains at least one hole (3) to constrain movement of said pin for restriction of translational motions in the plane of the plate surface, **characterized in that** said at least one hole (3) and said pin (8) are constructed to allow one or more degrees of freedom of movement of said pin (8) within the hole (3) without rigid fixation of said pin (8) to the plate (1).

2. The device of Claim 1, **characterized in that** the other end portion of the plate (1) is adapted to abut on the fractured bone fragment (9).

3. The device of Claim 1 or 2, **characterized in that** one hole (3) includes a slot (4) extending to an edge of said plate, said hole (3) being slightly undersized for constraining the motion of the pin.

4. The device of Claim 3, **characterized in that** the slot is undersized to provide snap engagement and to prevent movement of the pin out into the soft tissues.

5. The device of Claim 4, **characterized in that** said slot which provides snap engagement is constructed to permit said plate (1) to be engaged on said at least one pin (8) after the pin has been introduced into a fractured bone segment (9).

6. The device of Claims 1-5, **characterized in that** said end portions are shaped to conform to the respective shapes of said stable and fractured bone fragments.

7. The device of any of Claims 1-6, **characterized in that** said near end of said at least one pin (8) is bendable back to face said plate (1) and prevent separation of the plate and the pin.

8. The device of any of Claims 1-7, **characterized in that** said pin (8) has a smooth bone-engaging portion for penetrating into the fractured bone fragment (9).

9. The device of any of Claims 1-8, **characterized in that** at least one pin (8) has a diameter between 0,889 to 1,575 mm (0,035"-0,062") and is bendable.

Patentansprüche

1. Implantierbare Vorrichtung zur Fixierung wenigstens eines gebrochenen Knochenfragmentes (9) an ein stabiles Knochenfragment (10), wobei die implantierbare Vorrichtung eine implantierbare Platte (1) mit gegenüberliegenden Endabschnitten, Befestigungsmittel (7) zur Sicherstellung eines Endabschnittes der Platte an dem stabilen Knochenfragment, wenigstens einen Befestigungsstift (8), zum Anbringen über einem Bruch zur vorläufigen Stabilisierung des instabilen Knochenfragmentes (9) an dem stabilen Knochenfragment (10) umfasst, worin der andere Endabschnitt der Platte (1) wenigstens eine Bohrung (3) zum Erzwingen einer Bewegung des Stiftes zur Beschränkung von Translationsbewegungen in der Ebene der Plattenoberfläche umfasst, **dadurch gekennzeichnet, dass** die wenigstens eine Bohrung (3) und der Stift (8) so konstruiert sind, dass einer oder mehrere Freiheitsgrade der Bewegung des Stiftes (8) in der Bohrung (3) gestattet wird, ohne den Stift (8) mit der Platte (1) fest zu fixieren.

2. Vorrichtung nach Anspruch 1, **dadurch gekennzeichnet, dass** der andere Endabschnitte der Platte (1) zum Anstoßen an das gebrochene Knochenfragment (9) angepasst ist.

3. Vorrichtung nach Anspruch 1 oder 2, **dadurch gekennzeichnet, dass** eine Bohrung (3) einen Schlitz (4), welcher sich zu einer Kante der Platte erstreckt, umfasst, wobei die Bohrung (3) zum Erzwingen der Bewegung des Stiftes geringfügig unterdimensioniert ist.

4. Vorrichtung nach Anspruch 3, **dadurch gekennzeichnet, dass** der Schlitz unterdimensioniert ist, um einen Schnappeingriff vorzusehen und eine Bewegung des Stiftes in das weiche Gewebe zu verhindern.

5. Vorrichtung nach Anspruch 4, **dadurch gekennzeichnet, dass** der Schlitz, welcher einen Schnappeingriff vorsieht, so gestaltet ist, dass die Platte (1) an dem wenigstens einen Stift (8) befestigt werden kann, nachdem der Stift in ein gebrochenes Knochensegment (9) eingeführt worden ist.

6. Vorrichtung nach den Ansprüchen 1 bis 5, **dadurch gekennzeichnet, dass** die Endabschnitte so geformt sind, dass sie mit den jeweiligen Formen der stabilen und gebrochenen Knochenfragmente übereinstimmen.

7. Vorrichtung nach jedem der Ansprüche 1 bis 6, **dadurch gekennzeichnet, dass** das nahe Ende des wenigstens einen Stiftes (8) umklappbar ist, um an der Platte (1) anzuliegen und eine Trennung der Platte und des Stiftes zu verhindern.

8. Vorrichtung nach jedem der Ansprüche 1 bis 7, **dadurch gekennzeichnet, dass** der Stift (8) einen glatten, den Knochen in Eingriff nehmenden Abschnitt zum Einführungen in das gebrochene Knochenfragment (9) aufweist.

9. Vorrichtung nach jedem der Ansprüche 1 bis 8, **dadurch gekennzeichnet, dass** wenigstens ein Stift (8) einen Durchmesser zwischen 0,889 bis 1,575 mm (0,035 inch bis 0,062 inch) aufweist und biegbar ist.

Revendications

1. Dispositif implantable pour la fixation d'au moins un fragment (9) d'os fracturé à un fragment d'os stable (10), ledit dispositif implantable comprenant une plaque implantable (1) à extrémités opposées, un moyen de fixation (7) pour fixer une première extrémité de ladite plaque au fragment d'os stable, au moins une broche de fixation (8) à placer en travers d'une fracture pour stabiliser temporairement le fragment d'os instable (9) par rapport au fragment d'os stable (10), dans lequel l'autre extrémité de la plaque (1) contient au moins un trou (3) pour empêcher ladite broche de bouger afin de limiter les déplacements dans le plan de la surface de la plaque, **caractérisé en ce qu'**au moins un trou (3) et ladite broche (8) sont construits pour permettre un ou plusieurs degrés de liberté de mouvement de ladite broche (8) dans le trou (3) sans que ladite broche (8) ne soit fixée de manière rigide à la plaque (1).

2. Dispositif selon la revendication 1, **caractérisé en ce que** l'autre extrémité de la plaque (1) est conçue pour buter contre le fragment (9) d'os fracturé.

3. Dispositif selon la revendication 1 ou 2, **caractérisé en ce qu'**un trou (3) comporte une fente (4) s'étendant jusqu'à un bord de ladite plaque, ledit trou (3) étant légèrement sous-dimensionné pour empêcher la broche de bouger.

4. Dispositif selon la revendication 3, **caractérisé en ce que** la fente est sous-dimensionnée pour réaliser une mise en place par encliquetage et pour empêcher la broche de ressortir en pénétrant dans les tissus mous.

5. Dispositif selon la revendication 4, **caractérisé en ce que** ladite fente qui permet une mise en place par encliquetage est conçue pour permettre l'engagement de ladite plaque (1) sur ladite au moins une broche (8) après que la broche a été introduite dans un fragment (9) d'os fracturé.

6. Dispositif selon les revendications 1 à 5, **caractérisé en ce que** lesdites extrémités sont agencées pour épouser les formes respectives desdits fragments d'os stable et fracturé.

7. Dispositif selon l'une quelconque des revendications 1 à 6, **caractérisé en ce que** l'extrémité proximale de ladite au moins une broche (8) peut être rabattue en regard de ladite plaque (1) et empêcher la plaque et la broche de se séparer.

8. Dispositif selon l'une quelconque des revendications 1 à 7, **caractérisé en ce que** ladite broche (8) a une partie lisse s'engageant dans l'os, destinée à pénétrer dans le fragment (9) d'os fracturé.

9. Dispositif selon l'une quelconque des revendications 1 à 8, **caractérisé en ce qu'**au moins une broche (8) a un diamètre compris entre 0,889 et 1,575 mm (0,035" et 0,062") et est pliable.

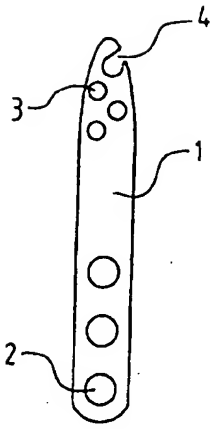

Fig. 1

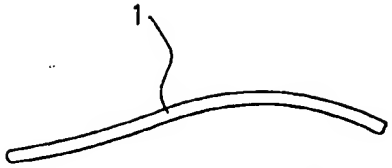

Fig. 2

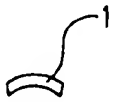

fig. 3

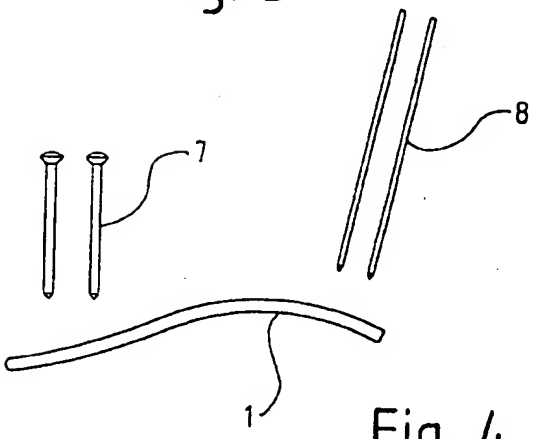

Fig. 4

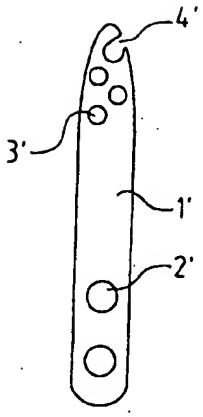

Fig. 7a

Fig. 7b

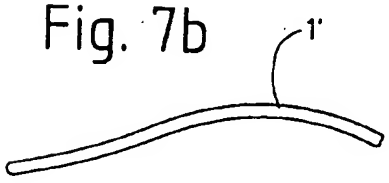

Fig. 7c

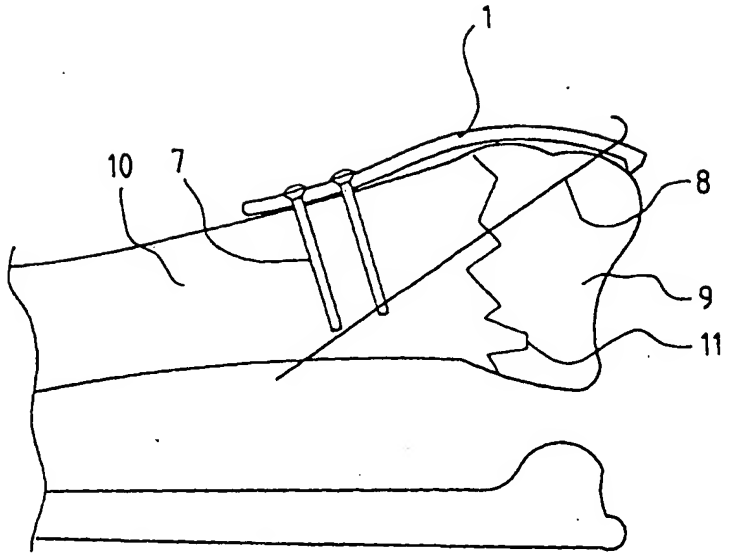

Fig. 5

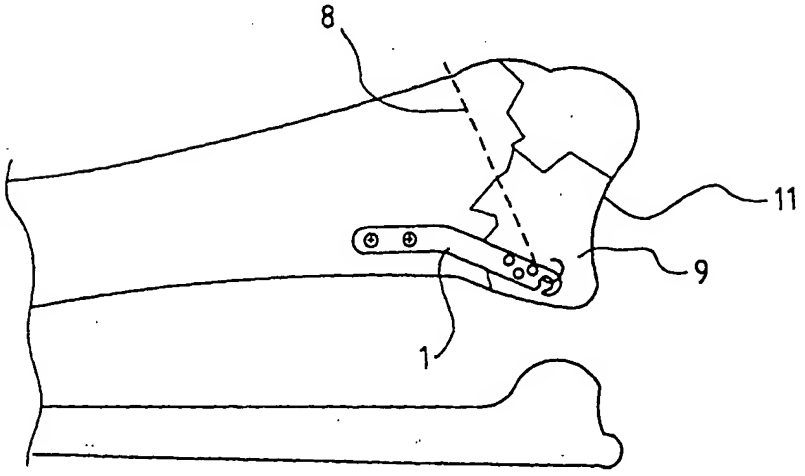

Fig. 6